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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,818

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Junzo Tanaka

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08/06/2008

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP  
1250 CONNECTICUT AVENUE, NW  
SUITE 700  
WASHINGTON, DC 20036

EXAMINER

NAFF, DAVID M

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1657

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,818	<b>Applicant(s)</b> TANAKA ET AL.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been  
5 timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/5/08 has been entered.

An amendment filed 5/5/08 amended claims 9, 11, 13, 15 and 16, canceled claim 12, and added new claim 17.

Claims examined on the merits are 9-11 and 13-17, which are all claims in the  
10 application.

### ***Claim Objections***

Claim 13 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim  
15 to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only difference in claims 11 and 13 is that the preamble claim 11 requires a scaffold and claim 13 requires an implant. A scaffold can be an implant and an implant can be a scaffold. Structure has not been claimed that will distinguish the scaffold and implant from each  
20 other.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the  
5 claimed invention.

The specification is confusing and unclear how alternatively soaking of the polymeric material in a calcium ion-containing solution and a phosphate ion-containing solution is to be carried out. At page 3, lines 26-29 and page 7, lines 24-28, the specification discloses soaking one side and then the other side. However, in a detailed example of alternate soaking (page 11,  
10 lines 18-27), only one side is alternatively soaked with the calcium ion-containing solution and phosphate ion-containing solution, and the other side is in contact with ultrapure water. Since the calcium and phosphate ions must react, it is not seen the ions can react when calcium ion is one side and phosphate ion is on the other side. As disclosed in the specification when carrying out the example of alternate soaking (page 12, lines 15-19), calcium and phosphate are  
15 distributed on the top side and the density becomes smaller toward the other side. This cannot occur if calcium is distributed on one side and phosphate is distributed on the other side.

The specification fails to provide an adequate description of how to produce the gradient when alternatively soaking one part and the other part as encompassed by lines 8-10 of claim 9 and lines 3-5 of claim 15. The specification fails to describe size of the parts and where the  
20 parts are located. Parts of just any size and location will not result in the claimed gradient. The only description of one part and the other part is at page 3, lines 26-29. More detailed description of alternatively soaking parts is not provided, and the detailed example of alternate soaking (page 11) does not describe alternatively soaking parts.

The specification fails to describe “continuous gradient” as required in claim 17. The amendment cites page 6, lines 2-6, as supporting a continuous gradient. However, “continuous gradient” is not recited at page 6, lines 2-6, and it is uncertain how this section of the specification supports the claim limitation.

5 ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 9-11 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear how alternatively soaking one side of the polymeric material in a calcium ion-containing solution and the other side in a phosphate ion-containing solution results in a calcium phosphate gradient in the polymeric material. To produce the gradient, calcium ions must react with phosphate ions. When the calcium ions and phosphate ions are on opposite sides of the material, it is not seen how they can react and produce a gradient of calcium phosphate. As note above, the detailed example on page 11 discloses alternatively soaking one side in calcium ions and phosphate ions such that density becomes smaller from a top side towards the other side of the matrix.

In line 4 of claim 9, “composition gradient” is uncertain as to meaning scope. It is uncertain how “composition” defines the gradient. Calcium phosphate is inherently a composition, and reciting “composition” does not further define the gradient, and should be deleted.

25 Claim 15 is unclear by not claiming a complete method containing all steps needed to produce a composite as required by claim 9. For example, in addition to alternatively soaking,

the method would require a step of providing a polymeric material selected from a group as required in claim 9, and would require the step of alternatively soaking to produce the polymeric material containing the gradient of calcium phosphate.

In line 2 of claim 17, "continuous gradient" is uncertain as to meaning and scope. The  
5 specification does not recite and define "continuous gradient".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness  
rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later  
20 invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattern et al (6,969,523) or Yannas et al (4,947,840) in view of Akashi et al (6,387,414) and Sherwood et al (6,454,811), and if necessary in further view of Taguchi et al (Biomaterials).

25 The claims are drawn to a composite material containing a gradient of calcium phosphate in a biodegradable polymeric material selected from collagen, glycosaminoglycan and a composite of collagen and glycosaminoglycan produced by alternatively soaking one side of the

material in a calcium ion-containing solution and the other side in a phosphate ion-containing solution.

Mattern et al (col 1, lines 11-30 and col 3, lines 50-67) and Yannas et al (paragraph bridging cols 1 and 2) disclose scaffolds formed of cross-linked collagen and  
5 glycosaminoglycan.

Akashi et al disclose preparing a hydroxyapatite composite by alternatively soaking a surface of a matrix in a calcium ion-containing solution and in a phosphate ion-containing solution. Matrices that can be used include collagen and a mucopolysaccharide such as hyaluronic acid (col 4, lines 15-17). The composite has a composition similar to bone and is  
10 useful as an artificial tissue such as artificial bone, or as medical materials (col 1, lines 6-12).

Sherwood et al disclose (col 4, lines 13-26 and 40-45) forming a gradient of calcium phosphate in a material such as collagen (col 8, line 50) to provide a composite implantable device for regeneration of bone.

Taguchi et al disclose preparing an apatite coating on hydrophilic polymer-grafted  
15 poly(ethylene) films by alternate soaking of the film in a calcium ion-containing solution and phosphate ion-containing solution. The resultant composite may be used as a hard tissue substitute and as a soft tissue adhesive.

It would have been obvious to provide hydroxyapatite in the cross-linked collagen/glycosaminoglycan scaffold of Mattern et al or Yannas et al by alternatively soaking the  
20 scaffold in a calcium ion-containing solution and a phosphate ion-containing solution as suggested by Akashi et al to provide a composite for use as artificial tissue such as artificial bone, and as suggested by Sherwood et al to make an implantable composite for bone regeneration. Hydroxyapatite is a calcium phosphate compound disclosed in the present specification (page 5, line 22) that can be the calcium phosphate of the claims. Using

alternative soaking as disclosed by Akashi et al will inherently provide a gradient of calcium phosphate as claimed. Moreover, Sherwood et al would have suggested a gradient.

Components of claims 11 and 13 would have been obvious since the components and their functions are known, and it would have been obvious to provide the components in a scaffold to obtain their expected functions. Providing cells as required by claim 14 would have been obvious to obtain the function of the cells to generate tissue. The scaffold of Mattern et al or Yannas et al is inherently porous as required by claim 16. If needed, Taguchi et al would have further suggested using alternate soaking as claimed to provide calcium phosphate in the scaffold of Mattern et al or Yannas et al.

### ***Response to Arguments***

The amendment urges that a continuous gradient cannot be achieved by the method described by Sherwood et al. However, a continuous gradient will inherently result when using the alternate soaking procedure suggested by Akashi et al, and if needed also suggested by Taguchi et al, to provide calcium phosphate in the scaffold of Mattern et al or Yannas et al for use as artificial tissue such as artificial bone.

### ***Claim Rejections - 35 USC § 103***

Claims 9, 15 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akashi et al.

The invention and Akashi et al are described above.

When preparing the hydroxyapatite composite of Akashi et al by alternatively soaking a surface of a matrix in a calcium ion-containing solution and in a phosphate ion-containing solution, it would have been obvious to use collagen as the matrix as suggested by Akashi et al disclosing that the matrix can be collagen. A gradient as required by the present claims will inherently result.



***Claim Rejections - 35 USC § 103***

Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akashi et al in view of Mattern et al or Yannas et al.

Claim 10 requires the polymeric material to be a crosslinked product of  
5 glycosaminoglycan and collagen.

Mattern et al and Yannas et al are described above.

It would have been obvious to replace the collagen of Akashi et al with the cross-linked collagen/glycosaminoglycan suggested by Mattern et al or Yannas et al to obtain the function of glycosaminoglycan in addition to collagen. Components of claims 11 and 13 would have been  
10 obvious since the components and their functions are known, and it would have been obvious to provide the components in a scaffold to obtain their expected functions. Providing cells as required by claim 14 would have been obvious to obtain the function of the cells to generate tissue.

***Conclusion***

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the  
20 organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

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8/1/08